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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,127

Applicant(s)

WIENER ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 1, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-21, 23-34, 37-40, and 43-46 is/are rejected.
- 7) ☒ Claim(s) 14, 15, 22, 35, 36, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-12, 17, 21, 24-32, 34, 38-40, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,017,354 to Culp et al. Culp discloses a system for implementing surgical procedures (30) according to the claimed invention. Culp also discloses a method for implementing surgical procedures in a system (30) according to the claimed invention. Culp's system includes an ultrasonic surgical hand piece (33), which has a sheath (50) [see Fig. 2] with an end-effector. The end-effector is a blade, referred to as a "saw" (35) in Column 5, lines 37-38 [see Fig. 1].

Note: An important aspect of Culp's disclosure that the applicant should understand relates to Culp's disclosure of an *ultrasonic surgical hand piece*. First of all, in the BACKGROUND OF THE INVENTION, Culp expresses that the reason for his invention—the problem to be solved—is that with all of the modern surgical tools now available it is expensive to keep separate generator consoles for each one [Column 1, lines 50-58]. He is setting out to provide a single integrated console that

is able to accept tools having many different power and controls requirements [Column 3, lines 44-51] that will save time for surgical staff.

He claims his invention broadly, but explains in the Specification that his invention is meant to encompass power tools of many types, including micro drills [Column 1, lines 44-49], power tools with integrated light and water sources [Column 2, lines 45-55], surgical lasers, and finally, *ultrasonic scalpels* [Column 3, lines 35-45]. Culp further discloses the use of an ultrasonic tool/hand piece in Column 24, lines 37-40 and in Column 57, lines 53-56. In summary, Culp discloses the use of both ultrasonic and non-ultrasonic surgical hand pieces for use with a console.

Culp's system also includes a generator console (36) for controlling the hand piece. The console (36) sends a drive current to drive the hand piece [Column 5, lines 38-41]. When an ultrasonic scalpel is used with this generator console [Culp discloses the use of both ultrasonic and non-ultrasonic surgical hand pieces] this drive current will inherently impart ultrasonic longitudinal movement to the blade.

Next, Culp discloses a memory disposed in the sheath (50) of the end-effector. The sheath (50) could also be called a "grip" or a "handle," as in Claim 2, because the hand piece is held with the user's hand. Memories 72 and 74 are fitted inside of the sheath (50) of the end-effector [see Column 6, lines 51-52; Figures 2 and 3]. The console reads information [see Column 6, line 65 – Column 7, line 1] stored in the memory (72 and 74) to determine whether or not a data string is present. For example, the console reads the memory 72 to check the serial number of the hand

piece [Column 15, lines 40-57. The hand piece can be authenticated for use if the data string (correct serial number, for example) is present.

2. Regarding Claims 1, 4, 5, and 45 Culp discloses a system with all of the limitations of the claims, including a data string, which is stored in the memory [see above]. The fact that the applicant's data string is *copyrighted* does not add any structural limitations on the data. For example, whether or not the string of numbers "57896768932775579" is copyrighted or not *does not change the value* of the numbers in the string. Consequently, the term "copyrighted," additionally found in Claims 32 is not considered to add any structural limitation to the invention.
3. Regarding Claim 9, Culp discloses a system for implementing surgical procedures, including a hand piece, a generator console, and a memory, as described above. Additionally, Culp's console writes historical usage and diagnostic information and configuration information into the memory. For example, the console writes the duration of activation of the hand piece into field 466 of the memory. This information can be used to diagnose the need for maintenance of the hand piece [Column 20, line 56 to Column 21 line 13]. Note that Figures 13 and 14 are block diagrams showing the data field in the read/write memory contained within the hand piece [see Column 4, lines 35-42].
4. Regarding Claims 10 and 12, Culp discloses a system for implementing surgical procedures, including a console that reads information stored in the memory [see above] and displays the information [Column 5, lines 42-48] and an interpretation of the information on the console display (37). An example of the screen displaying an

interpretation of information given in the memory is found in Column 17, lines 15-40.

The data (coefficients a, b, and c) is stored in the memory, and the data is interpreted using the equation shown in line 25 to output "y" on the display (37) of the console.

Further regarding Claims 10 and 12, Culp discloses a generator console, which includes a digital signal processor (518). The digital signal processor [microprocessor] exchanges digital signals with the memory of the hand piece [see Column 23, lines 40-48].

5. Regarding Claims 2, 6-8, 11, 21, 34, and 46, Culp discloses a system and a method for implementing surgical procedures, including all of the limitations of the claims, including an alarm/handicap mode and a disabling function. The console instructs the hand piece to operate in alarm/handicap mode by displaying a warning statement or sounding an audio warning tone and reducing the power. The console can then disable the hand piece if the temperature of the hand piece exceeds the disable limit [Column 54, lines 27-40; Column 51, lines 8-13].
6. Regarding Claim 17, Culp discloses that the memory in his device can be used with a hand piece that is a cauterizing tool [Column 57, 12-17].
7. Regarding Claim 24, *no physical structure is added to the invention by this claim by describing a method of using the invention*. The memory in the system records a handicap limit and a disable limit [see above #11].
8. Regarding Claims 25 and 38, Culp discloses a system and a method meeting all of the limitations of the respective claims in which the handicap limit and the disable limit are reinitialized based on varied operational conditions of the hand piece. Table

1 [Column 16] shows that the handicap and disable limits are stored in the memory, and Culp says that this memory is read each time the hand piece is initially configured [Column 6, line 51-Column 7, line 1]. Culp says that the user can vary the maximum speed at which the internal motor of the hand piece can operate, i.e. an "operational condition" of the hand piece [Column 16, line 66 to Column 17 line 14 and that this will reinitialize the data stored in the memory of the hand piece. The data stored in the hand piece affects the handicap limit and the disable limit [see Table 1].

9. Regarding Claims 26 and 39, the console is programmed by reading a reprogram code stored in the memory of the hand piece, and the console is upgraded by reading a code stored in the memory [Column 6, line 65-Column 7, line 1]. The data stored in the EEPROM is considered to be a code that upgrades and reprograms the console. The console determines whether or not codes are needed at various times: for example, if a new high temperature has been reached by the hand piece, then the console is reprogrammed with that information [Column 21, lines 14-27].

Further regarding Claim 26, *no physical structure is added to the invention by this claim by describing a method of using/programming the invention.*

10. Regarding Claim 27, *no physical structure is added to the invention by this claim by describing a method of using/programming the invention.* Furthermore, if it is determined that a reprogram of the console is *not needed*, then a non-hand piece device that plugs into the hand piece (with an associated memory) *is not needed*.

11. Regarding Claims 28 and 40, Culp discloses a system [and a method for using that system], which has information stored in the memory that correlates to energy level information and corresponding output displacement. The console reads the energy level information (based on the speed) and drives the hand piece according to the corresponding output displacement [see Column 47, lines 12-39; Fig. 28].

Additionally, information regarding the amount of current the motor should draw [Column 18, lines 17-22], the torque of the motor [Column 18, lines 53-55], and the maximum rate the motor should accelerate [Column 19, lines 50-55] are all different types of energy level information stored that correlate to output displacement.

Further regarding Claim 28, *no physical structure is added to the invention by this claim by describing a method of using/programming the invention.*

12. Regarding Claims 29 and 30, Culp discloses the system, as claimed, which stores information in the memory. No additional *structure* is added to the invention by describing what kind of information is stored in the memory.
13. Regarding Claim 31, the claim is taken to be a Markush claim, in which any one of the claimed aspects meets the claim. Culp discloses a memory that consists of an Electrically Erasable Programmable Read Only Memory, a Read Only Memory, an Erasable Programmable Read Only Memory, a Random Access Memory [Column 6, line 51 – Column 7 line 5], a Programmable Logic Array [Column 28, lines 12-19], - and a microprocessor [see above].
14. Further, with regards to Claims 1-3, 9, 10, 12, 32, and 44, Culp discloses a memory disposed in the sheath of an end effector, which optimizes operation of the

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generator console for operation with the end effector to achieve optimal tissue effects with the end effector, as claimed by the Applicant. Anything that affects the performance of the device will affect its response to/interaction with tissue. The memory of Culp's device stores data, as previously expounded, and is able to store data associated with the nature of the tissue to be cut with the scalpel. The memory of Culp's device is also able to store performance criteria such as energy level information. This information would help the generator console [and ultimately, the surgeon] *optimize the results of the tissue cutting surgery.*

15. Regarding Claim 47, Culp has disclosed using different hand pieces (which each would have different end effectors). Culp has acknowledged that these different tools have different power requirements [Column 3, lines 35-47]. Thus, Culp has disclosed optimizing surgeries—using the appropriate tool for different situations. Further, no structure is added to the apparatus claimed by including a method of using it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view of U.S. Patent No. 5,400,267 to Denen et al.

16. Regarding Claim 18, Culp discloses the system as claimed, but fails to explicitly disclose a memory that blocks the use of incompatible hand pieces. However, Denen discloses a memory located in an electric surgical device (scalpel) for use with a console that automatically establishes the compatibility of the scalpel (hand piece). If the hand piece is incompatible with the console, its use is blocked [Column 2, lines 36-45]. The disclosed reason for supplying this memory, which automatically verifies compatibility of the hand piece with the console, is so that damage is not done to equipment when incompatible hand pieces are inadvertently connected to consoles [Column 2, lines 16-27]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a memory with an electrical scalpel, as taught by Denen, in order to ensure damage is not done to the equipment by accidentally using a hand piece that is incompatible with a console.
17. Regarding Claim 19, Culp discloses the device as claimed, but fails to explicitly disclose a hand piece that is authenticated for use with the console using cyclical redundancy check. However, Denen discloses an electric surgical device (scalpel) that is authenticated for use by a console using cyclic redundancy check. It uses CRC to ensure that the console reads the authentication information stored in the hand piece without error [Column 16, line 65 to Column 17, line 19]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ cyclical redundancy check in an electric scalpel in order to make sure of the accuracy of the message sent from the hand piece to the console.

18. Regarding Claim 23, Culp fails to disclose a system in which there is a time limit for the use of the hand piece. However, Denen teaches that an electrical scalpel system ought to have a memory [see Figures 1 and 8] that stores a handicap limit [Column 13, lines 48-53] and a disable limit [Column 13, lines 41-48] that limit the length of time a hand piece can be used [Column 10, lines 42-45]. Denen's hand piece thus operates in handicap mode if the time the hand piece has been active exceeds the handicap limit, and the console disables the hand piece if the time the hand piece has been active exceeds the disable limit.

Culp's motivation for providing this handicap/disable feature is so that the surgeon can make sure that he or she replaces the hand piece before it fails, especially in critical medical applications [Column 1, lines 40-44]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a handicap mode and a disable limit for the hand piece to ensure that the user replaces the hand piece before it fails, while performing critical surgeries.

19. Claims 20, 24, 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view of U.S. Patent No. 6,331,181 to Tierney et al. Culp discloses the system according to Claim 20 and the method according to Claim 33, but does not explicitly disclose that the data string is an encrypted code, or that the hand piece is authenticated for use by decoding an encryption algorithm. However, Tierney teaches that one would use encryption *algorithm* to authenticate the use of a hand tool with a console so that the test would

not have to be done by hand. The algorithm automates the authentication process [Column 17, lines 22-42].

Tierney discloses a data string that is an encrypted code, and the hand piece is authenticated for use with the console by decoding a corresponding encryption algorithm in the console and provides a responding data pattern [Column 17, lines 22-42; see Fig. 15]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to authenticate a hand piece by means of an encrypted data string and an encryption algorithm, as taught by Teirney, in order to automate the process of authenticating the tool.

Regarding Claims 24 and 37, Culp discloses the method according to Claim 32 but does not disclose a means for keeping track of the number of activations for the hand piece within a time period. However, Tierney discloses a means for keeping track of the number activations for the hand piece within a time period [Column 18, Claim 14] for the purpose of disabling the hand piece, and states that one would employ a means to keep track of the number of activations in a given time period so that one would not need to do it by hand (resorting to an external table) [Column 2, lines 54-65] and so as to increase the safety of using an electronic hand piece [Column 2, lines 30-36]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a means to keep track of the number of activations in a given time period for the purpose of disabling the hand piece, as taught by Teirney, in order to automate the process of recording the rate of activation and to increase the safety of using electrical hand pieces.

20. Regarding Claim 43, Culp discloses the method according to Claim 32 but does not disclose a means for keeping track of the number of uses of the end-effector. However, Tierney discloses a means for keeping track of the number of uses for the end-effector and a means for keeping track of a number of remaining uses allowed for the end-effector [Column 2, lines 54-65]. The *number of remaining uses* are considered to be included under "tool life data," because Tierney teaches broadly about many kinds of tool life data, including many characteristics of the end-effector [Column 15, line 59-Column 16 line 19].
21. Claims 20 and 33 are also rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view U.S. Patent No. 6,298,255 to Cordero et al. Culp discloses the system according to Claim 20 and the method according to Claim 33, but does not explicitly disclose that the data string is an encrypted code, or that the hand piece is authenticated for use by decoding an encryption algorithm. However, Cordero teaches that one would want to use encryption with a hand piece/console system so as to protect the console from being used with a counterfeit hand piece [Column 3, lines 32-37]. Figure 16 shows the authentication process, including decoding a corresponding encryption algorithm in the console and providing a responding data pattern (926). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to authenticate a hand piece by means of an encrypted data string and an encryption algorithm, as taught by Cordero, to protect the console from being used with a counterfeit hand piece.

22. Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view U.S. Patent No. 6,434,507 to Clayton et al. Culp discloses the invention as claimed, and as described above, but fails to disclose a memory communicating electrically with a switch adaptor through direct contacts. However, Clayton (among others) teaches that one would use direct contacts with memory that communicates electrically with a switch adaptor with high speed hand piece/controller assembly so as to make sure that no information is lost when the end-effector is changed by the user [Column 1, lines 56-63]. Figure 6 shows the circuitry involved, and the direct contacts specifically. Using direct contacts for this purpose is well known in the art of ultrasonic hand pieces. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ direct contacts to connect the memory [end-effector] to the switch adaptor of Culp's device in order to make sure that information is maintained accurately despite the changing of end-effectors by various users [Column 2, lines 30-35], as taught by Clayton.

Allowable Subject Matter

23. Claim 14, 15, 22, 35, 36, 41, and 42 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

25. Applicant's arguments filed April 1st, 2004 have been fully considered but they are not persuasive. Applicant asserts in the last line of page 16 and the first line of page 17 that, "Fast cutting results in poor hemostasis, while slow cutting results in good hemostasis." This statement is important because Applicant is implying that *hemostasis is a direct result of the speed at which the end-effector vibrates*. That is, the "degree of tissue hemostasis," as set forth in claims 1, 2, 3, 9, 10, 12, 32, and 44, is proportional to the speed (rate) that the end-effector moves.

Culp discloses a system having an end-effector that vibrates at a variable rate. Figure 4, for example, is a graph showing how the speed of the end effector varies

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with the torque applied by the motor [Column 4, lines 37-39]. Further, Column 44, lines 56-61 and Column 1, lines 25-35 explain that in all state-of-the-art surgical hand pieces, and specifically in Culp's surgical hand piece, the tool speed is variable and is controlled by the amount of energy supplied to the tool. These tools have either a hand or foot switch, which controls the amount of voltage driving the tool.

Applicant's statement is confirmed by other patent disclosures. Previously cited U.S. Patent No. 5,026,387 to Thomas explains that the degree of tissue hemostasis is a function of the driving power applied and the type of tissue being cut [Column 4, lines 19-25]. *Culp's tool is driven at various speeds and can be used to cut various types of tissue.*

Because Culp's tool has an end-effector having a variable speed adjustable by the user, it will inherently (according to the applicant's aforementioned statement and the prior art teaching) set the degree of tissue hemostasis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

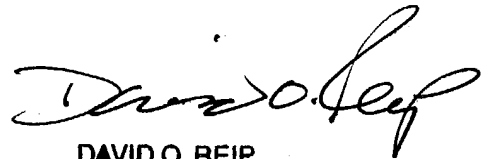
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June 1, 2004



DAVID O. REIP
PRIMARY EXAMINER